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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/627,908

07/25/2003

Jiande Chen

79109 (6328)

3453

22242

7590

07/06/2006

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 07/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/627,908

Applicant(s)

CHEN, JIANDE

Examiner

Michael Kahelin

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/26/2006 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation "consisting essentially of" is lacking support in the cited Examples 1 and 2. Although the examples do not positively recite stimulation of other organs, the examples also do not exclude stimulation of other organs.

Any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement (See MPEP 2173.05(i)).

Response to Arguments

4. Applicant's arguments filed 4/26/2006 have been fully considered but they are not persuasive. Applicant amended the independent claims to recite a method "consisting essentially of" the previously rejected method steps. Applicant further argued that this limitation requires that stimulation is to the small intestine only, which is unanticipated by Chen et al. (US 5,690,691, hereinafter "Chen"). This is not found convincing because there is no clear indication of the "basic and novel characteristics" of the claimed invention (i.e. no indication that exclusive small intestine stimulation is the "basic and novel" feature). As such:

For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 (MPEP 2111.03).

5. Furthermore, although Chen does describe an embodiment wherein multiple organs are stimulated, Chen also discloses stimulating individual organs of the gastrointestinal tract (abstract and col. 3, line 41) and prolonging the time food is kept in

the stomach to counteract the "fast rate" at which food is passed from the stomach to the small intestine (col. 8, line 39) through retrograde pacing. Chen further discloses:

"if there is rapid small bowel transit or "dumping" then disrupting this movement with retrograde pacing could be good therapy".

6. This is a clear disclosure of small intestinal stimulation for treatment of obesity through the mechanism of slowing food transit through the gastrointestinal tract; stomach included. Since the gastro-intestinal tract is a closed system, slowing motility in the small intestine will inherently slow stomach emptying and slow food transit through the digestive system.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-6 and 11-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (5,690,691).

9. In regards to claims 1 and 11, Chen et al. disclose multiple implantable devices comprising leads (70'-87') with connectors for attachment to a pulse generator (18, 20, and 22), wherein the leads are adjacent to the small intestine and provide electrical stimulation (Fig. 5, elements 74-81).

Art Unit: 3762

10. In regards to claims 2, 12, and 13, electrical stimulation is provided to the duodenum (74) and the jejunum (77).

11. In regards to claims 3-6 and 14-17, the electrical stimulation provided is in the range of 2 to 15 pulses per minute (col. 9, line 29), about 0.1 to about 4 seconds (col. 9, line 36), and has a pause of 3-30 seconds between pulses (inherent of a frequency of 9-12.5 pulses per minute and duration of 0.1 sec.).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 7-10, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. in view of Mintchev et al. (6,449,511). Chen et al. disclose the essential features of the claimed invention except for pulses comprising micro-bursts within the frequency range of 5 to 100 Hz. Mintchev et al. teach of a gastrointestinal stimulator which applies electrical stimulation in bursts in the frequency range of 5-500 Hz (col. 19, line 15) to produce local circumferential contractions without causing any significant damage to the tissues (col. 19, line 51). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Chen et al.'s invention by providing stimulation in bursts of 5 to 100 Hz


to produce local circumferential contractions without causing any significant damage to the tissues.

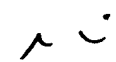
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK

6/19/06


GEORGE R. EVANISKO
PRIMARY EXAMINER
6/29/06